REMARKS

The foregoing complete set of amended claims is provided for the convenience of the Examiner pursuant to 37 C.F.R. § 1.121(c)(3). If it is determined that renumbering of the claims set forth in Paper No. 12 was not mistaken after consideration of Applicants remarks below, then entry of the foregoing prior to examination of the application on the merits is respectfully requested. This set of amended claims reflects the renumbering of the claims set forth in the Official Action with amendments to restore the original claim dependencies. No new matter is introduced by these amendments.

Claim renumbering

In the Official Action, claims 35-55 have been renumbered as claims 38-58. Applicants note that this application is a continuation/divisional of an application filed under 35 U.S.C. § 371. Original claims 1-37 of the international application were replaced by claims 1-34, presented on substitute sheets during the international stage of the application. The substitute sheets comprising claims 1-34 were attached to the translation of the international application as separately translated substitute sheets in the present application as in the parent file. The currently pending claims represent a reintroduction of claims 15-31 of the claims presented on the substitute sheets, which were first canceled by preliminary amendment.

The renumbering of the claims in the Official Action suggests that the substitute sheets of the international application were not recognized in the present application. The present amendment is offered to provide a complete set of claims renumbered as set forth in the Official Action and having the correct dependencies. However, the renumbering

may have been mistaken. If the renumbering is found to have been mistaken, and the original numbering is restored, then the present amendments should not be entered.

Applicants respectfully request that the Examiner provide a statement making the record clear with respect to the claim numbering and the entry or non-entry of the present amendments in the next Official Action.

Election with traverse

Applicants hereby make the following election **with traverse**.

Applicants elect the species of the invention of Group VII, claims 40, 41, 43-49 and 51-58, which is drawn to a recombinant adenoviral vector comprising an exogenous nucleotide sequence encoding all or part of an antibody and placed under the control of the elements necessary for its expression, wherein said antibody is modified by a immunopotentiating substance. It is noted that the Official Action acknowledges that Groups I-VIII are linked by claims 40, 41, 44-48, and 51-58. Therefore, the restriction requirement is subject to being withdrawn upon a finding that a linking claim is allowable.

Among the subspecies of Group VII set forth on page 5 of the Official Action, Applicants elect the subspecies of a CD4 protein for examination. It is noted that this is a species election. Therefore, upon a finding that the elected species is free of the prior art, the examination will be expanded to encompass additional species.

The restriction requirement is respectfully traversed as being overly divisive between aspects of the invention contrary to Office policy as described in the M.P.E.P. at § 803, stating "If the search and examination of an entire application can be made without

serious burden, the examiner must examine it on the merits, even though it include claims to independent or distinct inventions." (emphasis added) Furthermore, the Official Action does not provide a sufficient reason for insisting upon the restriction as required by M.P.E.P. § 808.

Applicants submit that in view of the overlapping subject matter of the Groups, search and examination of the entire invention would be substantially covered by the searching of any one Group. This is clearly evidenced by the fact that each group is classified in the same class and subclass. Thus, a thorough search of this single subclass should turn up the most relevant art. Searching the entire application as claimed would not present a serious burden and all Groups should be examined together. M.P.E.P. § 803.

The Office Action states that the inventions of Groups I-VII are unrelated. To be unrelated requires a showing that the inventions are not disclosed of being capable of being used together. M.P.E.P. § 808.01. However, the aspect of the invention of elected Group VII, the modification of the antibody with an immunopotentiating substance, can clearly be used together with a aspect of the invention encompassed by any of Groups I - VI, modification of the antibody by a toxic substance. The use of these aspects together is described in the specification and illustrated, for example, by the embodiments embraced by Group VIII and claim 50.

Where the inventions proposed to be restricted are related, the Examiner bears the burden of showing that restriction is proper by showing one of the following: (A) Separate classification. However, Groups I-VIII are classified in the same class and subclass. (B)

Separate status in the art. A bald assertion is made that the inventions have a separate status in the art. However, no evidence or explanation is given regarding why they have a separate status in the art is presented in the Office Action. (C) A different field of search. No evidence or explanation of why a separate field of search would be required is presented in the Office Action. "Where . . . the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among related inventions." M.P.E.P. § 808.02. Accordingly, the Official Action does not make the required showing to support the restriction requirement.

A basis for the policy against restricting an application where a search can be performed without serious burden can be found in a general policy against wasting the Applicants', the Office's, or the public's time and resources in pursuit of a hyper-technical application of the rules. The present restriction requirement, assuming only for the sake of argument that it is technically proper, is a hyper-technical application of the rules and will waste the resources of all three of the Applicants, the Office, and the public if not withdrawn or at least modified.

The Applicant's time and resources will be unnecessarily wasted. In order to obtain the protection to which Applicants are entitled, the Applicants will be forced to file, prosecute, and maintain an unnecessarily large series of divisional applications. Each application will require a series of repetitive clerical formalities as well as expenditure of professional time and government fees.

If the unnecessary expense of Applicants' time and resources is not a concern of the Office, the waste of Office resources and public resources should be of concern. For each divisional application that the Applicants must file, a series of redundant clerical and administrative expenses are incurred by the Office. Even if the cost of these resources is covered by the fees charged, the expenses of managing the resulting increased volume of repetitive administrative materials, and waste of examiners' limited time conducting substantially overlapping examinations, is an inefficient use of public resources.

Finally, the public is burdened by such a hyper-technical restriction requirement in its need to expend greater resources to determine the bounds of what is protected and what is not protected. The patent provides the public with notice of what can be freely practiced. However, if the present restriction requirement stands, the public will be forced to review an extended series of patents, issued over a period of time, to determine what parts of the disclosure have been protected. To perform a complete analysis will require the review of an equal number of full file histories. Such an expense un-necessarily burdens businesses which must be concerned with these matters in order to operate and innovate. Resources spent on tracking an unnecessarily numerous series of divisional patent applications and granted patents cannot be spent advancing the useful arts.

In view of the foregoing, applicants respectfully submit that the restriction requirement is not proper. Even if technically within the guidelines of the M.P.E.P., such a hyper-technical restriction would be contrary to the stated policy of the Office as described in M.P.E.P. § 803, because no serious burden would be imposed if the entire application were examined on the merits.

Applicants respectfully request reconsideration and withdrawal of the restriction requirement so that the entire application may be expeditiously examined on its merits. At the very least, Applicants request that the species election within Group VII be withdrawn and the Group examined as a whole. Further Applicants request that at least Group VIII should be recombined with Group VII, because Group VIII is so related to Group VII that no reasonable burden can be imputed to examining these groups together.

A Notice of Allowance is believed to be next in order and is earnestly requested. Should there be any questions regarding the present Reply, a telephone call to the undersigned is respectfully requested so that prosecution of the subject application may be expedited.

Respectfully submitted,

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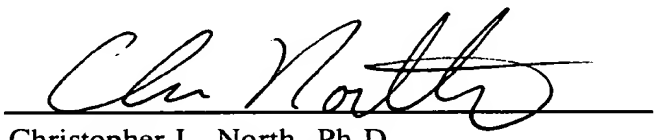
By: 

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Attachment to the Reply dated February 28, 2003
Marked-up Claims

41. (Amemded) The recombinant adenoviral vector according to Claim [37] 40, wherein said antibody is selected from the group consisting of a native antibody, a chimeric antibody, an antibody fragment and a bispecific antibody.

42. (Amemded) The recombinant adenoviral vector according to Claim [37] 40, wherein said antibody may be modified by a toxic substance selected from a ribonuclease, ricin, diphtheria toxin, cholera toxin, herpes simplex virus thymidine kinase, cytosine deaminase from Escherichia coli or from a yeast of the genus Saccharomyces, exotoxin from Pseudomonas and human angiogenin or an analog of the said substances.

43. (Amemded) The recombinant adenoviral vector according to Claim [37] 40, wherein said antibody is modified by an immunopotentiating substance.

44. (Amemded) A recombinant adenoviral vector comprising an exogenous nucleotide sequence encoding all or part of one or more protein(s) of interest capable of forming a multimer, such as a dimer or a tetramer, in a host cell; said exogenous nucleotide sequence being placed under the control of the elements necessary for its expression, said vector being derived from an adenovirus of human, canine, avian, bovine, murine, ovine, porcine or simian origin or a hybrid comprising adenoviral genome fragments of different origins.

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45. (Amemded) The recombinant adenoviral vector according to Claim [37] 40, derived from an adenovirus of human, canine, avian, bovine, murine, ovine, porcine or simian origin or from a hybrid comprising adenoviral genome fragments of different origins.

46. (Amemded) The recombinant adenoviral vector according to Claim [37] 40, wherein it is defective for replication.

47. (Amemded) The recombinant adenoviral vector according to Claim [43] 46, wherein it lacks at least all or part of the E1 region and, optionally, all or part of the E3 region.

48. (Amemded) The recombinant adenoviral vector according to Claim [43] 46, comprising an exogenous nucleotide sequence encoding the heavy chain of the 2F5 antibody, an IRES element and the light chain of the 2F5 antibody; said exogenous nucleotide sequence being placed under the control of elements necessary for its expression.

49. (Amemded) The recombinant adenoviral vector according to Claim [43] 46, comprising an exogenous nucleotide sequence encoding the signal sequence and the extracellular I and II domains of the CD4 protein operably fused to the constant γ3 region (hinge region-CH2 and CH3) of the heavy chain of the 2F5 antibody.

Attachment to the Reply dated February 28, 2003
Marked-up Claims

50. (Amemded) The recombinant adenoviral vector according to Claim [43] 46, comprising an exogenous nucleotide sequence encoding the signal sequence and the extracellular I and II domains of the CD4 protein operably fused to the constant γ3 region (hinge region-CH2 and CH3) of the heavy chain of the 2F5 antibody and operably fused to the mature human angiogenin.

51. (Amemded) The recombinant adenoviral vector according to Claim [37] 40, wherein the elements necessary for the expression comprise a promoter selected from the group consisting of the adenoviral early promoter E1A, the late promoter MLP (Major Late Promoter), the murine or human PGK (Phosphoglycerate kinase) promoter, the SV40 virus early promoter, the RSV (Rous Sarcoma virus) virus promoter, a promoter which is specifically active in tumor cells and a promoter which is specifically active in the infected cells.

52. (Amemded) An infectious viral particle comprising a recombinant adenoviral vector according to Claim [37] 40.

53. (Amemded) A eukaryotic host cell comprising a recombinant adenoviral vector according to Claim [37] 40.

Attachment to the Reply dated February 28, 2003
Marked-up Claims

54. (Amemded) A pharmaceutical composition comprising a recombinant adenoviral vector according to Claim [37] 40, in association with a pharmaceutically acceptable carrier.

55. (Amemded) The pharmaceutical composition according to Claim [51] 54, comprising 10^4 to 10^{14} pfu.

56. (Amemded) The pharmaceutical composition according to Claim [51] 54, wherein it is in injectable form.

57. (Amemded) The recombinant adenoviral vector according to Claim [41] 44, wherein it is defective for replication.

58. (Amemded) The recombinant adenoviral vector according to Claim [41] 44, wherein the elements necessary for the expression comprise a promoter selected from the group consisting of the adenoviral early promoter E1A, the late promoter MLP (Major Late Promoter), the murine or human PGK (Phosphoglycerate kinase) promoter, the SV40 virus early promoter, the RSV (Rous Sarcoma virus) virus promoter, a promoter which is specifically active in tumor cells and a promoter which is specifically active in the infected cells.